European Union: The Make-Over of the Single Market: What is in the New Package

Sylvia Mohr
04/2008
MR-#133

Summary

The free movement of goods in the European Union is still hindered by local requirements despite harmonization of EU regulation throughout the single market of 27 member states*. In an effort to remove these obstacles and to improve the functioning of the single market, the Commission prepared a package of measures in 2007, which was adopted in first reading by the European Parliament in February 2008. The package of measures, which consists of well-known existing instruments, such as market surveillance and new approach legislation (CE marking), is now awaiting a vote in the Council of Ministers of the European Union. By fine-tuning the tools, the Commission hopes to create better regulatory instruments leading ultimately to streamlining and simplification of the regulatory environment. As it is meant to improve free flow of goods in the single market, it will benefit exporters. While the consultation on the review covered the single market from all angles, including the consumer's perspective, this report only considers significance of the package for U.S. exporters. Please note that as the proposed texts go through the legislative process, they may still be subject to change.

Background

The single market was launched at the end of 1992 with the removal of internal borders in the European Union. At the time of launch, existing and new legislation to facilitate free flow of goods were based on a set of core instruments:

- harmonized rules through legislation (known as "old approach" covering foodstuffs, motor vehicles, pharmaceuticals and more)
- harmonized rules through use of essential requirements, EN standards, conformity assessment modules and accredited test laboratories (known as "new and global approach", and easily identifiable because of the "CE marking")
- co-regulation or self-regulation relying on post market surveillance (all products falling under the EU general product safety directive)
- notifications by members states of national requirements to protect workers in the workplace, public health, environment

Despite the harmonized regulatory infrastructure, the single market remains a "work in progress". It is not unusual for manufacturers of products to adapt their goods to requirements in place in individual markets. For example, manufacturers of textile draperies have to adjust to differing national classification requirements based on the use of the draperies. In its leaflet on the "Single Market of Goods" (link provided below **), the Commission identified certain technical specifications as obstacles, such as composition, dimensions, presentation and packaging of goods as well as lack of harmonization of use of EU languages on labels. Moreover, competition among manufacturers was somewhat distorted due to the different practices of designation of conformity assessment bodies. Lack of recognition of the CE marking, the symbol of conformity, as well as lack of coherence in implementation and enforcement posed additional obstacles. Last year's recall of toys illustrated some of the shortcomings of CE marking under the current system.

New Proposed Package

In 2003, the Council of Ministers of the European Union invited the Commission to review the new and global approach. The goal was better regulation and simplification. In 2007, the Commission proposed several new legislative texts, which build on existing tools and instruments presented in a new "Single Market Package of Goods":

- COM(2007) 36 final - Regulation of the European Parliament and the Council laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision 3052/95/EC
- COM(2007) 37 final – Regulation of the European Parliament and the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products
- COM(2007) 53 final – Decision of the European Parliament and the Council on a common framework for the marketing of products.

Other documents in this package, not awaiting adoption, are the impact assessments and the Communication COM(2007) 35 final on " The Internal Market for Goods: a cornerstone of Europe's competitiveness."

The package of instruments was presented as a toolbox for regulators when considering new legislation or whenever review of existing legislation offers the possibility to simplify. It is meant to facilitate EU trade by referencing European standards where possible. By promoting this new package, the EU positions itself as "model that other countries are prepared to follow" (see leaflet **).

The proposals have already been adopted by the European Parliament in first reading and are now awaiting a vote in the Council of Ministers of the European Union, possibly by June 2008, although that may slip. For market surveillance, member states will have two years following adoption of the regulation to implement the new measures, that is, if the proposed regulation is adopted as currently drafted.

This is what the package of measures consists of:

1) Proposed Regulation of the European Parliament and the Council laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision 3052/95/EC

Products legally on the market in one country should be accepted in another EU country without undergoing additional testing or verification. The proposed regulation intends to shift the burden of proof to the country of destination. Hypothetically, this means that if a manufacturer certifies compliance of his/her product with EU regulations, and if the importer's national authority challenges compliance, the onus will be on the authority to justify in writing the technical or scientific reason for refusing market access.

It is possible for member states to put in place technical measures for products not harmonized or regulated in existing EU legislation, such as ladders, bicycles, furniture. The new proposed regulation lays out procedures for future notifications and foresees the creation of a network of national "Product Contact Points". The Product Contact Points will provide information about the national technical rules applicable to a specific product in the national territory, contact details of authorities, information about remedies and guidance about other information sources.

In support of this proposed regulation, the Commission announced its intention to create a website listing non-regulated products. This website will offer competent bodies and manufacturers a source of reference for products that should be accepted in all EU countries based on the principles of mutual recognition. Conversely, it will also list products to which EU "secondary" legislation applies. By

"secondary", the Commission means EU legislation about performance, testing/test methods, symbols, conformity assessment, etc.

As a first step, the Commission's Directorate on Regulatory Policy (C) in Directorate General Enterprise and Industry launched a tender in March 2008 to recruit services for the "establishment of a list of products to which Articles 28 and 30 of the EC Treaty apply". (Note: Articles 28 and 30 prohibit quantitative restrictions on free flow of goods between member states except for specific reasons as stated in the articles). The tender covers three "lots" which are grouped according to the EU's customs classification system. It includes, among others, plastics and articles made of plastic, mineral products, umbrellas, optical instruments, arms and ammunition, and works of art. Deadline for completion of contract from the date of award is 7 months.

2) Proposed Regulation of the European Parliament and the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products

The proposed horizontal measures are meant to reinforce and streamline existing market surveillance and accreditation and to consider ways to extend the tools to other sectors currently not covered by either the new or old approach. As market surveillance and customs inspections are outside the Commission's scope of legislative power, the proposed text does not go into a lot of detail, encouraging authorities to perform "appropriate checks … on an adequate scale" in order to ensure that products presenting a "serious risk" are recalled or withdrawn, without defining "serious risk".

A change compared to the current situation is that the number of accreditation bodies will be limited to one per country, making it a public rather than private (competitive) activity. The task of assessment and monitoring of notified bodies can be handled by national accreditation bodies or by a designated notifying authority. To facilitate implementation, the Commission intends to draft a guideline.

3) Proposed Decision of the European Parliament and the Council on a common framework for the marketing of products

Overview - The proposed framework accomplishes the Commission's goal of bringing coherence in existing new approach legislation by spelling out definitions, responsibilities, procedures and more. The proposed text incorporates interpretations provided in the non-binding existing Guide on New and Global Approach, also known as the "Blue Guide", as well as other guidance documents currently used by notified bodies. It lists a number of existing directives excluded from the scope such as feed and food law and medicinal legislation, among others.

Use of standards - With regard to use of standards, the principles remain unchanged, basically that only use of harmonized standards, adopted by one of the European standards organizations - CEN, CENELEC and ETSI as mentioned in EU directive 98/34/EC - will give presumption of conformity. If a harmonized standard falls short of meeting the mandate or essential requirements, the Commission has the right to refuse publication in the Official Journal based on the findings of the relevant Committee as described in 98/34/EC.

Role of authorized representativeimporter/distributor - Depending on the product, conformity assessment may be carried out by the manufacturer, a notified body or a public authority. The role of the authorized representative has been limited as he cannot design/manufacture nor draw up the technical documentation although he can apply CE marking to the product. Importers or distributors, on the other hand, can become manufacturers whenever they bring a product on the market under their own name or trademark, or significantly modify the product so that compliance with the relevant requirements is affected. In practical terms, U.S. manufacturers who do not want to handle CE marking, can transfer the task to the importer or distributor with the understanding that the latter then takes the responsibility of a

"manufacturer" in accordance with the proposed text. This relationship will have to be documented in writing.

Market surveillance - To some extent market surveillance will be carried out by the importer, as he/she will have to verify whether the appropriate conformity assessment procedure has been carried out by the manufacturer. The proposed text further stipulates that the name and address of the importer shall be on the product or the packaging or in an accompanying document. Importers may take corrective measures whenever products are non-compliant or subject to recall. Distributors are supposed to verify conformity markings and accompanying documents. Both importer and/or distributor, as the case may be, are bound to actively cooperate when requested by market surveillance authorities.

Notified bodies - Market surveillance will also be a task for notified bodies (also referred to as conformity assessment bodies). Whenever notified bodies find that manufacturers' products do not meet a harmonized standard or requirements in the directive, they shall require manufacturers to make the necessary changes. Notified bodies may suspend or withdraw their certificate of conformity if the problem has not been resolved. Such action will have to be notified to the notifying authority. In addition, the proposed text addresses the responsibilities of notified bodies acting as consultants, clarifying that the notified bodies cannot offer consultancy services related to conformity assessment activities for which they are notified and relating to products intended to be placed on the Community market. However, exchanges of technical information as well as the use of assessed products that are necessary for the activity of the notified body is acceptable. It is not clear whether this rule extends to subsidiaries although it is implied since notified bodies have to ensure that their subcontractors perform in accordance with the proposed regulation. In general, "the conformity assessment body shall ensure that activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity, and impartiality of its conformity assessment activities."

Safeguard procedures - Safeguard procedures have also been tightened. According to the proposed text, market surveillance authorities will evaluate the product, involving the manufacturer in dialogue from the beginning, whenever products are found to pose a serious risk, presents a risk to the health or safety of persons or for other reasons of public interest protection. Manufacturers may be asked to take appropriate measures or, depending on the severity of the problem, withdraw or recall their products. If the non-compliant product is available on other markets, market surveillance authorities will inform the Commission and other member states. If no adjustments have been made, the product will be barred from the market, and other member states as well as the Commission will be alerted immediately. Safeguard procedures will be subject to a time line.

Conformity assessment modules - The existing new approach modules remain unchanged. As with the original text 93/465/EEC, which will be replaced upon adoption of the proposed regulation, the regulator has a menu of module options ranging from least to most stringent, proportionate to the level of risk involved and the level of safety required.

Significance of this New Package for U.S. Exporters

As member states transpose the proposed texts following adoption, they are supposed to take the necessary steps to create a more level playing field among competitors in the coming years. Better accreditation guidelines and improved cooperation of notified bodies should lead to fewer differences in interpretation and conformity assessment. Nevertheless, changes might not be very obvious for U.S. exporters because the infrastructure allowing free flow of goods already exists even though it is imperfect. Over the next two years, market surveillance and customs inspections are expected to improve their operation and tighten their coordination. Increasingly, importers are more likely to ask questions about the manufacturer's CE marking process since their responsibilities will be enhanced. In addition, it will become easier to determine rules applicable to unregulated products, which are currently not listed

anywhere. If delivered as planned, the website will facilitate access to information. It might also identify gaps for future harmonization efforts.

In terms of policy, it means that the available tools have been repackaged and improved. New and Global Approach, the concept created in the mid-eighties introducing essential requirements, conformity assessment modules, harmonized standards, notified bodies, and CE marking will continue to exist as part of the package of instruments, but its content will be more uniform. As it turned out to be successful, it is going to be used as a regulatory model for use in other areas of EU regulatory activity. It has already been applied in legislation about eco-design and energy efficiency. Existing "old approach" legislation will continue to exist, such as automotive and foodstuffs. The most obvious change will be in the area of general product safety – unregulated products – and national notifications because of the planned creation of an information network as well as a website listing products and requirements by country.

Next Steps

The package is now awaiting a vote in the Council of Ministers of the European Union. Prior to final adoption, it is likely that the texts as proposed by the Commission may be subject to amendments introduced by the European Parliament as well as the Council of Ministers of the European Union. One of the many changes proposed by the European Parliament is about an in-depth analysis by the Commission about consumer safety marking, to be presented in one year's time following adoption of the Decision on marketing of goods. It may pave the way for new legislative proposals. The Commission already launched a consultation on a future consumer safety mark in April 2008.

Links

Website of the New Package:
http://ec.europa.eu/enterprise/regulation/internal_market_package/index_en.htm

Announcement of the new Package:
http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/276&format=HTML&aged=0&language=EN&guiLanguage=en

Leaflet on New Package (**)
http://ec.europa.eu/enterprise/newsroom/cf/itemshortdetail.cfm?item_id=1351

Status of the legislative process:
http://www.europarl.europa.eu/oeil/file.jsp?id=5448032
http://ec.europa.eu/prelex/detail_dossier_real.cfm?CL=en&DosId=195358
(http://ec.europa.eu/prelex/rech_simple.cfm?CL=en)

Notice of the tender:
http://ted.europa.eu/Exec?DataFlow=ShowPage.dfl&Template=TED/N_one_result_detail_curr.htm&docnumber=58871-2008&docId=58871-2008&StatLang=EN

European Accreditation:
http://www.european-accreditation.org/default_flash.htm

Articles 28 and 30:
http://eur-lex.europa.eu/en/treaties/dat/12002E/htm/C_2002325EN.003301.html#anArt28

New Approach legislation:
www.newapproach.org
http://ec.europa.eu/enterprise/newapproach/index_en.htm

Notification of national measures:
http://ec.europa.eu/enterprise/regulation/goods/3052intro_en.htm#Decision_3052/95/CE

Consultation new consumer safety mark:
http://ec.europa.eu/yourvoice/ipm/forms/dispatch?form=SAFETYMARK2

* EU Member States:
Austria, Belgium, Bulgaria, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, the Netherlands, Poland, Portugal, Romania, Slovenia, Slovakia, Spain, Sweden, and the United Kingdom

For More Information

The U.S. Commercial Service in at the US Mission to the European Union can be contacted via e-mail at: Sylvia.Mohr@mail.doc.gov; Phone: 32-2-508-2111; Fax: 32-2-513-1228; or visit our website: www.buyusa.gov/eu.

The U.S. Commercial Service — Your Global Business Partner

With its network of offices across the United States and in more than 80 countries, the U.S. Commercial Service of the U.S. Department of Commerce utilizes its global presence and international marketing expertise to help U.S. companies sell their products and services worldwide. Locate the U.S. Commercial Service trade specialist in the U.S. nearest you by visiting http://www.export.gov/.

Comments and Suggestions: We welcome your comments and suggestions regarding this market research. You can e-mail us your comments/suggestions to: **Customer.Care@mail.doc.gov**. Please include the name of the applicable market research in your e-mail. We greatly appreciate your feedback.